

AMENDED IN ASSEMBLY JUNE 20, 2013

AMENDED IN SENATE MAY 7, 2013

AMENDED IN SENATE APRIL 18, 2013

SENATE BILL

No. 306

Introduced by Senator ~~Price~~ Torres
(Principal coauthor: Assembly Member ~~Gordon~~ Cooley)

February 15, 2013

An act to amend Sections ~~1000, 2530.2, 2531, 2531.75, 2533, 2570.19, 2602, and 2607.5~~ 4170, 4180, and 4186 of the Business and Professions Code, relating to ~~healing arts~~ pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 306, as amended, ~~Price Torres. Healing arts: boards. Pharmacy:~~ *dangerous drugs and dangerous devices: automated drug delivery systems.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies in this state by the California State Board of Pharmacy. A violation of the Pharmacy Law is a crime.

Among other provisions, the Pharmacy Law prohibits a prescriber from dispensing dangerous drugs or dangerous devices, as defined, to patients in his or her office unless specified conditions are met. Existing law defines a prescriber for purposes of this provision to mean a person who holds a physician's and surgeon's certificate, or one of other specified health care licenses or certificates, and who is registered to engage in that practice with the appropriate board of this state. Existing law authorizes certain health care professionals, including a certified nurse-midwife or a nurse practitioner, as specified, to hand to a patient of the supervising physician and surgeon a properly labeled prescription

drug prepackaged by a physician and surgeon, a manufacturer, as defined, or a pharmacist.

This bill would revise the conditions under which a prescriber may dispense dangerous drugs and dangerous devices. The bill would require a health care professional who is licensed as specified, or his or her designee, to physically furnish the dangerous drug or device to the patient, to be identified, except as specified, by the drug or device manufacturer or wholesaler supplying the drug or device as the recipient of the drug or device, and as the recipient in all invoices, bills of lading, state or federal order forms, and other documentation, and to provide the patient with an oral consultation, as specified. The bill would revise the definition of a prescriber to apply to a person who is licensed to prescribe and dispense dangerous drugs, including, but not limited to, the licensed health care professionals authorized pursuant to existing law. The bill would also authorize a registered nurse who functions within a licensed primary care clinic, federal or state government operated clinic, community or free clinic to hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer, as defined, or a pharmacist.

Existing law authorizes clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic. Existing law also authorizes an automated drug delivery system, as defined, to be located in any clinic licensed by the board, as specified. Existing law requires an automated drug delivery system to collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

This bill would authorize an automated drug delivery to be located in a group practice, as specified. The bill would authorize specified entities, including a group practice, that uses an automated drug delivery system, as described, to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon or other prescriber when permitted by law, and would make conforming and related changes.

The bill would also impose new conditions on an automated drug delivery system. Among other requirements, the bill would require that an automated drug delivery system be located within the clinic or office of the group practice, that its contents be secure from access or removal by unauthorized individuals, and that it maintain a readily retrievable

electronic record to identify all pharmacists, registered pharmacy technicians, prescribers, and all other personnel involved in the dispensing of a drug. The bill would also require that the record of transactions conducted through the automated drug delivery system be made available to authorized agents of the board. The bill would authorize the board to adopt regulations permitting the use of an automated drug delivery system that delivers dispensed medications directly to a patient.

Because of violation of the bill's requirements would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

~~The Chiropractic Act, enacted by an initiative measure, provides for the regulation and licensing of chiropractors in this state by the State Board of Chiropractic Examiners. Existing law specifies that the law governing chiropractors is found in the act.~~

~~This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature. The bill would require that the review of the board be performed as if these provisions were scheduled to be repealed on January 1, 2018.~~

~~Existing law, the Speech-Language Pathologists and Audiologists and Hearing Aid Dispensers Licensure Act, provides for the licensure and regulation of speech-language pathologists, audiologists, and hearing aid dispensers by the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board. The act authorizes the board to appoint an executive officer. Existing law repeals these provisions on January 1, 2014, and subjects the board to review by the Joint Committee on Boards, Commissions, and Consumer Protection.~~

~~This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the board to review by the appropriate policy committees of the Legislature.~~

~~The Speech-Language Pathologists and Audiologists and Hearing Aid Dispensers Licensure Act also authorizes the board to refuse to issue, or issue subject to terms and conditions, a license on specified grounds, including, among others, securing a license by fraud or deceit.~~

~~This bill would additionally authorize the board to refuse to issue, or issue subject to terms and conditions, a license for a violation of a term or condition of a probationary order of a license issued by the board, as provided.~~

~~Existing law, the Occupational Therapy Practice Act, provides for the licensure and regulation of occupational therapists, as defined, by the California Board of Occupational Therapy. Existing law repeals those provisions on January 1, 2014, and subjects the board to review by the Joint Committee on Boards, Commissions, and Consumer Protection.~~

~~This bill would extend the operation of these provisions until January 1, 2018, and provide that the repeal of these provisions subjects the board to review by the appropriate policy committees of the Legislature.~~

~~Existing law, the Physical Therapy Practice Act, provides for the licensure and regulation of physical therapists by the Physical Therapy Board of California. The act authorizes the board to appoint an executive officer. Existing law repeals these provisions on January 1, 2014.~~

~~This bill would extend the operation of these provisions until January 1, 2018.~~

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: ~~no~~ yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4170 of the Business and Professions
- 2 Code is amended to read:
- 3 4170. (a) No prescriber shall dispense *dangerous* drugs or
- 4 dangerous devices to patients in his or her office or place of
- 5 practice unless all of the following conditions are met:
- 6 (1) The dangerous drugs or dangerous devices are dispensed to
- 7 the prescriber's own patient, ~~and the drugs or dangerous devices~~
- 8 ~~are not furnished by a nurse or physician attendant patient. A health~~
- 9 ~~care professional who is licensed as described in this section, or~~
- 10 ~~his or her designee, shall physically furnish the dangerous drug~~
- 11 ~~or device to the patient.~~
- 12 (2) The dangerous drugs or dangerous devices are necessary in
- 13 the treatment of the condition for which the prescriber is attending
- 14 the patient.

1 (3) The prescriber does not keep a pharmacy, open shop, or
2 drugstore, advertised or otherwise, for the retailing of dangerous
3 drugs, dangerous devices, or poisons.

4 (4) The prescriber fulfills all of the labeling requirements
5 imposed upon pharmacists by Section 4076, all of the
6 recordkeeping requirements of this chapter, and all of the packaging
7 requirements of good pharmaceutical practice, including the use
8 of childproof containers.

9 ~~(5) The prescriber does not use a dispensing device unless he~~
10 ~~or she personally owns the device and the contents of the device,~~
11 ~~and personally dispenses the dangerous drugs or dangerous devices~~
12 ~~to the patient packaged, labeled, and recorded in accordance with~~
13 ~~paragraph (4).~~

14 (5) *Unless the prescriber is employed by or under contract to*
15 *a clinic or group practice that is licensed by the board pursuant*
16 *to Section 4180, the prescriber is identified by the drug*
17 *manufacturer or wholesaler supplying the drugs as the recipient*
18 *of the drugs and identified by name and registration number as*
19 *the recipient in all invoices, bills of lading, state or federal order*
20 *forms, and other documentation. As the recipient of the drugs, the*
21 *prescriber is responsible for ensuring that the drugs are securely*
22 *and safely stored prior to dispensing and is responsible for*
23 *maintaining all required records regarding the receipt, storage,*
24 *and dispensing or other disposition of all drugs and devices.*

25 (6) The prescriber, prior to dispensing, offers to give a written
26 prescription to the patient that the patient may elect to have filled
27 by the prescriber or by any pharmacy.

28 (7) The prescriber provides the patient with written disclosure
29 that the patient has a choice between obtaining the prescription
30 from the dispensing prescriber or obtaining the prescription at a
31 pharmacy of the patient's choice.

32 (8) *The prescriber provides the patient with an oral consultation*
33 *regarding issues that the prescriber, in his or her professional*
34 *judgment, deems necessary to ensure the safe and effective use of*
35 *the prescribed drug or device. The oral consultation shall include*
36 *all subjects that pharmacists are required to discuss pursuant to*
37 *regulations adopted by the board pursuant to Section 4005.*

38 (8)

39 (9) A certified nurse-midwife who functions pursuant to a
40 standardized procedure or protocol described in Section 2746.51,

1 a nurse practitioner who functions pursuant to a standardized
2 procedure described in Section 2836.1, or protocol, a physician
3 assistant who functions pursuant to Section 3502.1, *a registered*
4 *nurse who functions pursuant to Section 2725.1*, or a naturopathic
5 doctor who functions pursuant to Section 3640.5, may hand to a
6 patient of the supervising physician and surgeon a properly labeled
7 prescription drug prepackaged by a physician and surgeon, a
8 manufacturer as defined in this chapter, or a pharmacist. *Nothing*
9 *in this section shall preclude the use of an automated drug delivery*
10 *system described in Section 4186.*

11 (b) The Medical Board of California, the State Board of
12 Optometry, the Bureau of Naturopathic Medicine, the Dental Board
13 of California, the Osteopathic Medical Board of California, the
14 Board of Registered Nursing, the Veterinary Medical Board, and
15 the Physician Assistant Committee shall have authority with the
16 California State Board of Pharmacy to ensure compliance with
17 this section, and those boards are specifically charged with the
18 enforcement of this chapter with respect to their respective
19 licensees.

20 (c) “Prescriber,” as used in this section, means *a person who is*
21 *licensed to prescribe and dispense dangerous drugs and devices,*
22 *including, but not limited to, a*~~person~~*, person who holds a*
23 *physician’s and surgeon’s certificate, a license to practice*
24 *optometry, a license to practice naturopathic medicine, a license*
25 *to practice dentistry, a license to practice veterinary medicine, or*
26 *a certificate to practice podiatry, and who is duly registered by the*
27 *Medical Board of California, the State Board of Optometry, the*
28 *Bureau of Naturopathic Medicine, the Dental Board of California,*
29 *the Veterinary Medical Board, or the Board of Osteopathic*
30 *Examiners of this state.*

31 (d) *This section shall not prevent a group practice, licensed*
32 *pursuant to Section 4180, from owning an inventory of dangerous*
33 *drugs and devices and dispensing the drugs and devices from the*
34 *inventory owned by the group practice provided that the following*
35 *conditions are met:*

36 (1) *Each prescriber dispenses dangerous drugs or devices only*
37 *to the patients seen or treated by that prescriber, and not to the*
38 *patient of any other prescriber in the group practice, and the drugs*
39 *or devices are packaged, labeled, and recorded in accordance*
40 *with paragraph (4) of subdivision (a).*

1 (2) *The group practice identifies a responsible prescriber within*
2 *the group practice who shall be named by the drug manufacturer*
3 *or wholesaler supplying the drugs as the recipient of the drugs on*
4 *all invoices, bills of lading, state or federal order forms, and other*
5 *documentation, and who shall be responsible for the*
6 *record-keeping and storage of the drug inventory.*

7 (3) *Records are maintained by each prescriber to identify the*
8 *identity of the patient and the name, strength, quantity, and*
9 *directions for use for each dangerous drug dispensed by the*
10 *prescriber to his or her patient.*

11 (4) *A daily dispensing log or some other paper or electronic*
12 *record is created each day, and maintained by the group practice,*
13 *to identify both of the following:*

14 (A) *A daily starting inventory of all dangerous drugs that are*
15 *jointly owned by the prescribers who comprise the group practice.*

16 (B) *The name, strength, and quantity of all dangerous drugs*
17 *dispensed by each prescriber.*

18 (e) *A prescriber employed by, or under contract to, a clinic or*
19 *group practice licensed under Section 4180 may dispense drugs*
20 *that are owned by the clinic or group practice.*

21 (f) (1) *For purposes of this section, a dangerous drug is owned*
22 *if it is delivered to the possession of a prescriber, clinic, or group*
23 *practice, and each prescriber, clinic, or group practice has*
24 *responsibility for the security and recordkeeping associated with*
25 *possession of the dangerous drugs, regardless of the person or*
26 *entity responsible for payment for the dangerous drug inventory.*

27 (2) *For the purposes of this section, “group practice” means*
28 *more than one prescriber practicing under a single professional*
29 *corporation or license, including a medical group or risk-bearing*
30 *organization as defined in the Knox-Keene Health Care Service*
31 *Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340)*
32 *of Division 2 of the Health and Safety Code).*

33 SEC. 2. *Section 4180 of the Business and Professions Code is*
34 *amended to read:*

35 4180. (a) (1) *Notwithstanding any provision of this chapter,*
36 *any of the following—~~clinics~~ entities may purchase drugs at*
37 *wholesale for administration or dispensing, under the direction of*
38 *a physician and surgeon, or other prescriber when permitted by*
39 *law, to patients registered for care at the clinic:*

1 (A) A licensed nonprofit community clinic or free clinic as
2 defined in paragraph (1) of subdivision (a) of Section 1204 of the
3 Health and Safety Code.

4 (B) A primary care clinic owned or operated by a county as
5 referred to in subdivision (b) of Section 1206 of the Health and
6 Safety Code.

7 (C) A clinic operated by a federally recognized Indian tribe or
8 tribal organization as referred to in subdivision (c) of Section 1206
9 of the Health and Safety Code.

10 (D) A clinic operated by a primary care community or free
11 clinic, operated on separate premises from a licensed clinic, and
12 that is open no more than 20 hours per week as referred to in
13 subdivision (h) of Section 1206 of the Health and Safety Code.

14 (E) A student health center clinic operated by a public institution
15 of higher education as referred to in subdivision (j) of Section 1206
16 of the Health and Safety Code.

17 (F) A nonprofit multispecialty clinic as referred to in subdivision
18 (l) of Section 1206 of the Health and Safety Code.

19 (G) *A group practice, as defined in Section 4170, that uses an*
20 *automated drug delivery system, as described in Section 4186.*

21 (2) The clinic *or group practice* shall keep records of the kind
22 and amounts of drugs purchased, administered, and dispensed, and
23 the records shall be available and maintained for a minimum of
24 three years for inspection by all properly authorized personnel.

25 (b) No clinic *or group practice* shall be entitled to the benefits
26 of this section until it has obtained a license from the board. A
27 separate license shall be required for each clinic location. A clinic
28 *or group practice* shall notify the board of any change in the
29 clinic's address *of the clinic or group practice* on a form furnished
30 by the board.

31 SEC. 3. Section 4186 of the Business and Professions Code is
32 amended to read:

33 4186. (a) ~~Automated~~ *An automated drug delivery system*
34 *system, as defined in subdivision (h) (i), may be located in any*
35 *clinic or group practice licensed by the board pursuant to as*
36 *described in Section 4180.* ~~If~~

37 (b) (1) *If* an automated drug delivery system is located in a
38 clinic, the clinic shall develop and implement written policies and
39 procedures to ensure safety, accuracy, accountability, security,
40 patient confidentiality, and maintenance of the quality, potency,

1 and purity of drugs. All policies and procedures shall be maintained
2 at the location where the automated drug system is being used.

3 (2) *If an automated drug delivery system is located in a group*
4 *practice, the group practice shall develop and implement written*
5 *policies and procedures to ensure safety, accuracy, accountability,*
6 *security, patient confidentiality, and maintenance of the quality,*
7 *potency, and purity of drugs. All prescribers who will be dispensing*
8 *drugs from the automated drug delivery system and all health care*
9 *professionals and delegated personnel authorized to stock, refill,*
10 *or retrieve the drugs inventory from the automated drug delivery*
11 *system shall be required to comply with the policies and procedures*
12 *developed by the group practice. All policies and procedures shall*
13 *be maintained at the location where the automated drug system is*
14 *being used.*

15 ~~(b)~~

16 (c) Drugs shall be removed from the automated drug delivery
17 system only upon authorization by a pharmacist *or prescriber* after
18 the pharmacist *or prescriber* has reviewed the prescription and the
19 patient's profile for potential contraindications and adverse drug
20 reactions. Drugs removed from the automated drug delivery system
21 shall be provided to the patient by a health professional licensed
22 pursuant to this division *or an individual operating under the*
23 *supervision of the prescriber.*

24 ~~(e)~~

25 (d) The stocking of an automated drug delivery system shall be
26 performed by a pharmacist *or, in a clinic or group practice, by a*
27 *prescriber or a designee of the prescriber.*

28 ~~(d)~~

29 (e) Review of the drugs contained within, and the operation and
30 maintenance of, the automated drug delivery system shall be the
31 responsibility of the clinic *in a clinic setting or by the responsible*
32 *prescriber in a group practice.* The review shall be conducted on
33 a monthly basis by a pharmacist *or responsible prescriber* and
34 shall include a physical inspection of the drugs in the automated
35 drug delivery system, an inspection of the automated drug delivery
36 system machine for cleanliness, and a review of all transaction
37 records in order to verify the security and accountability of the
38 system.

39 ~~(e)~~

(f) The automated drug delivery system used at the clinic or group practice shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video, *unless a consultation is provided by the prescriber pursuant to paragraph (8) of subdivision (a) of Section 4170.*

~~(f) The~~

(g) A pharmacist operating the automated drug delivery system shall be ~~located~~ *licensed* in California.

~~(g)~~

(h) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

~~(h)~~

(i) For purposes of this section, an “automated drug delivery system” means a mechanical system controlled remotely by a pharmacist, *or, if used to facilitate prescriber dispensing by a prescriber,* that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and ~~accountability~~. *accountability and shall meet all of the following requirements:*

(1) *The system shall be located within the clinic or office of the group practice, and its contents shall be secure from access or removal by unauthorized individuals.*

(2) *A policy and procedure manual shall be developed and maintained and shall include the type or name of the system including a serial number or other identifying nomenclature and a description of the security provisions, stocking processes, and other documentation practices of the clinic or group practice.*

(3) *The system shall have a method to ensure security of the system to prevent unauthorized access to dangerous drugs or devices contained within the system. The method may include the use of electronic passwords, biometric identification, including optic scanning or fingerprint, or other coded identification.*

(4) *The clinic or group practice shall employ a process of filling and stocking the system with drugs. The stocking or restocking of a drug shall only be completed by a pharmacist, prescriber, or*

1 *personnel designated by the pharmacist or prescriber and all of*
2 *the following shall apply:*

3 *(A) The cartridges or containers to be stocked or restocked shall*
4 *be provided by a licensed wholesale drug distributor or repackaged*
5 *by the pharmacy or prescriber in compliance with state and federal*
6 *law. The licensed wholesale drug distributor shall have a method*
7 *of receiving and disposing of rejected, expired, or unused*
8 *medications consistent with state or federal law.*

9 *(B) The individual cartridge or container shall be transported*
10 *to the dispensing site in a secure, tamper-evident package.*

11 *(C) The system shall use a bar code verification, electronic*
12 *verification, weight verification, radio frequency identification,*
13 *or similar process to ensure that the cartridge or container is*
14 *accurately stocked or restocked into the automated system. The*
15 *system shall provide for alerts to the responsible pharmacist or*
16 *prescriber if a cartridge or container is not recorded in the*
17 *automated system.*

18 *(D) The pharmacist or prescriber responsible for the dispensed*
19 *drug shall be responsible if the cartridge or container is stocked*
20 *or restocked incorrectly by the personnel designated to load the*
21 *cartridges or containers.*

22 *(5) The system shall maintain an electronic or hard copy record*
23 *of medication filled into the system, including the product*
24 *identification, lot number, and expiration date.*

25 *(6) The system shall maintain a readily retrievable electronic*
26 *record to identify all pharmacists, registered pharmacy technicians,*
27 *prescribers, and all other personnel involved in the dispensing of*
28 *a drug.*

29 *(7) The system shall be able to comply with product recalls*
30 *generated by any manufacturer or distributor and shall have a*
31 *process in place to isolate affected lot numbers.*

32 *(8) The record of transactions conducted through the automated*
33 *drug delivery system shall be available to authorized agents of the*
34 *board. The record of transactions shall, only to the extent*
35 *authorized or permitted by state or federal law, include the*
36 *following:*

37 *(A) Name of the patient.*

38 *(B) Name, strength, and dosage form of the drug product*
39 *dispensed.*

40 *(C) Quantity of drug dispensed.*

1 (D) Date and time of dispensing.

2 (E) Prescription number or other unique serial number assigned
3 to the transaction.

4 (F) Name of prescriber.

5 (G) Identity of the pharmacist who approved the prescription,
6 or of the prescriber.

7 (H) Identity of the person to whom the drug was released.

8 (9) Unless the prescriber provides consultation pursuant to
9 regulations adopted by the board pursuant to Section 4005, the
10 system shall provide patients with telephonic access to consultation
11 by a California-licensed pharmacist.

12 (10) In the case of dangerous drugs that require reconstitution,
13 the prescriber or his or her designee shall reconstitute the
14 medication for the patient.

15 (j) The board is authorized to adopt regulations authorizing the
16 use of an automated drug delivery system that delivers dispensed
17 medications directly to a patient. The regulations shall be based,
18 in part, upon the board's assessment of the safety of the systems.

19 SEC. 4. No reimbursement is required by this act pursuant to
20 Section 6 of Article XIII B of the California Constitution because
21 the only costs that may be incurred by a local agency or school
22 district will be incurred because this act creates a new crime or
23 infraction, eliminates a crime or infraction, or changes the penalty
24 for a crime or infraction, within the meaning of Section 17556 of
25 the Government Code, or changes the definition of a crime within
26 the meaning of Section 6 of Article XIII B of the California
27 Constitution.

28 SECTION 1. ~~Section 1000 of the Business and Professions~~
29 ~~Code is amended to read:~~

30 ~~1000. The law governing practitioners of chiropractic is found~~
31 ~~in an initiative act entitled "An act prescribing the terms upon~~
32 ~~which licenses may be issued to practitioners of chiropractic,~~
33 ~~creating the State Board of Chiropractic Examiners and declaring~~
34 ~~its powers and duties, prescribing penalties for violation hereof,~~
35 ~~and repealing all acts and parts of acts inconsistent herewith,"~~
36 ~~adopted by the electors November 7, 1922. Notwithstanding any~~
37 ~~other law, the powers and duties of the State Board of Chiropractic~~
38 ~~Examiners, as set forth in this article and under the act creating~~
39 ~~the board, shall be subject to review by the appropriate policy~~

committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

SEC. 2. Section 2530.2 of the Business and Professions Code is amended to read:

2530.2. As used in this chapter, unless the context otherwise requires:

(a) “Board” means the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board.

(b) “Person” means any individual, partnership, corporation, limited liability company, or other organization or combination thereof, except that only individuals can be licensed under this chapter.

(c) A “speech-language pathologist” is a person who practices speech-language pathology.

(d) The practice of speech-language pathology means all of the following:

(1) The application of principles, methods, instrumental procedures, and noninstrumental procedures for measurement, testing, screening, evaluation, identification, prediction, and counseling related to the development and disorders of speech, voice, language, or swallowing.

(2) The application of principles and methods for preventing, planning, directing, conducting, and supervising programs for habilitating, rehabilitating, ameliorating, managing, or modifying disorders of speech, voice, language, or swallowing in individuals or groups of individuals.

(3) Conducting hearing screenings.

(4) Performing suctioning in connection with the scope of practice described in paragraphs (1) and (2), after compliance with a medical facility’s training protocols on suctioning procedures.

(e) (1) Instrumental procedures referred to in subdivision (d) are the use of rigid and flexible endoscopes to observe the pharyngeal and laryngeal areas of the throat in order to observe, collect data, and measure the parameters of communication and swallowing as well as to guide communication and swallowing assessment and therapy.

(2) Nothing in this subdivision shall be construed as a diagnosis. Any observation of an abnormality shall be referred to a physician and surgeon.

~~(f) A licensed speech-language pathologist shall not perform a flexible fiberoptic nasendoscopic procedure unless he or she has received written verification from an otolaryngologist certified by the American Board of Otolaryngology that the speech-language pathologist has performed a minimum of 25 flexible fiberoptic nasendoscopic procedures and is competent to perform these procedures. The speech-language pathologist shall have this written verification on file and readily available for inspection upon request by the board. A speech-language pathologist shall pass a flexible fiberoptic nasendoscopic instrument only under the direct authorization of an otolaryngologist certified by the American Board of Otolaryngology and the supervision of a physician and surgeon.~~

~~(g) A licensed speech-language pathologist shall only perform flexible endoscopic procedures described in subdivision (e) in a setting that requires the facility to have protocols for emergency medical backup procedures, including a physician and surgeon or other appropriate medical professionals being readily available.~~

~~(h) "Speech-language pathology aide" means any person meeting the minimum requirements established by the board, who works directly under the supervision of a speech-language pathologist.~~

~~(i) (1) "Speech-language pathology assistant" means a person who meets the academic and supervised training requirements set forth by the board and who is approved by the board to assist in the provision of speech-language pathology under the direction and supervision of a speech-language pathologist who shall be responsible for the extent, kind, and quality of the services provided by the speech-language pathology assistant.~~

~~(2) The supervising speech-language pathologist employed or contracted for by a public school may hold a valid and current license issued by the board, a valid, current, and professional clear clinical or rehabilitative services credential in language, speech, and hearing issued by the Commission on Teacher Credentialing, or other credential authorizing service in language, speech, and hearing issued by the Commission on Teacher Credentialing that is not issued on the basis of an emergency permit or waiver of requirements. For purposes of this paragraph, a "clear" credential is a credential that is not issued pursuant to a waiver or emergency permit and is as otherwise defined by the Commission on Teacher~~

1 ~~Credentialing. Nothing in this section referring to credentialed~~
2 ~~supervising speech-language pathologists expands existing~~
3 ~~exemptions from licensing pursuant to Section 2530.5.~~

4 ~~(j) An “audiologist” is one who practices audiology.~~

5 ~~(k) “The practice of audiology” means the application of~~
6 ~~principles, methods, and procedures of measurement, testing,~~
7 ~~appraisal, prediction, consultation, counseling, instruction related~~
8 ~~to auditory, vestibular, and related functions and the modification~~
9 ~~of communicative disorders involving speech, language, auditory~~
10 ~~behavior or other aberrant behavior resulting from auditory~~
11 ~~dysfunction; and the planning, directing, conducting, supervising,~~
12 ~~or participating in programs of identification of auditory disorders,~~
13 ~~hearing conservation, cerumen removal, aural habilitation, and~~
14 ~~rehabilitation, including, hearing aid recommendation and~~
15 ~~evaluation procedures including, but not limited to, specifying~~
16 ~~amplification requirements and evaluation of the results thereof,~~
17 ~~auditory training, and speech reading, and the selling of hearing~~
18 ~~aids.~~

19 ~~(l) A “dispensing audiologist” is a person who is authorized to~~
20 ~~sell hearing aids pursuant to his or her audiology license.~~

21 ~~(m) “Audiology aide” means any person meeting the minimum~~
22 ~~requirements established by the board. An audiology aid may not~~
23 ~~perform any function that constitutes the practice of audiology~~
24 ~~unless he or she is under the supervision of an audiologist. The~~
25 ~~board may by regulation exempt certain functions performed by~~
26 ~~an industrial audiology aide from supervision provided that his or~~
27 ~~her employer has established a set of procedures or protocols that~~
28 ~~the aide shall follow in performing these functions.~~

29 ~~(n) “Medical board” means the Medical Board of California.~~

30 ~~(o) A “hearing screening” performed by a speech-language~~
31 ~~pathologist means a binary puretone screening at a preset intensity~~
32 ~~level for the purpose of determining if the screened individuals~~
33 ~~are in need of further medical or audiological evaluation.~~

34 ~~(p) “Cerumen removal” means the nonroutine removal of~~
35 ~~cerumen within the cartilaginous ear canal necessary for access in~~
36 ~~performance of audiological procedures that shall occur under~~
37 ~~physician and surgeon supervision. Cerumen removal, as provided~~
38 ~~by this section, shall only be performed by a licensed audiologist.~~
39 ~~Physician and surgeon supervision shall not be construed to require~~

1 the physical presence of the physician, but shall include all of the
2 following:

3 (1) ~~Collaboration on the development of written standardized~~
4 ~~protocols. The protocols shall include a requirement that the~~
5 ~~supervised audiologist immediately refer to an appropriate~~
6 ~~physician any trauma, including skin tears, bleeding, or other~~
7 ~~pathology of the ear discovered in the process of cerumen removal~~
8 ~~as defined in this subdivision.~~

9 (2) ~~Approval by the supervising physician of the written~~
10 ~~standardized protocol.~~

11 (3) ~~The supervising physician shall be within the general~~
12 ~~vicinity, as provided by the physician-audiologist protocol, of the~~
13 ~~supervised audiologist and available by telephone contact at the~~
14 ~~time of cerumen removal.~~

15 (4) ~~A licensed physician and surgeon may not simultaneously~~
16 ~~supervise more than two audiologists for purposes of cerumen~~
17 ~~removal.~~

18 SEC. 3. ~~Section 2531 of the Business and Professions Code is~~
19 ~~amended to read:~~

20 2531. (a) ~~There is in the Department of Consumer Affairs the~~
21 ~~Speech-Language Pathology and Audiology and Hearing Aid~~
22 ~~Dispensers Board in which the enforcement and administration of~~
23 ~~this chapter are vested. The Speech-Language Pathology and~~
24 ~~Audiology and Hearing Aid Dispensers Board shall consist of nine~~
25 ~~members, three of whom shall be public members.~~

26 (b) ~~This section shall remain in effect only until January 1, 2018,~~
27 ~~and as of that date is repealed, unless a later enacted statute, that~~
28 ~~is enacted before January 1, 2018, deletes or extends that date.~~
29 ~~Notwithstanding any other law, the repeal of this section renders~~
30 ~~the board subject to review by the appropriate policy committees~~
31 ~~of the Legislature.~~

32 SEC. 4. ~~Section 2531.75 of the Business and Professions Code~~
33 ~~is amended to read:~~

34 2531.75. (a) ~~The board may appoint a person exempt from~~
35 ~~civil service who shall be designated as an executive officer and~~
36 ~~who shall exercise the powers and perform the duties delegated~~
37 ~~by the board and vested in him or her by this chapter.~~

38 (b) ~~This section shall remain in effect only until January 1, 2018,~~
39 ~~and as of that date is repealed, unless a later enacted statute, that~~
40 ~~is enacted before January 1, 2018, deletes or extends that date.~~

SEC. 5. ~~Section 2533 of the Business and Professions Code is amended to read:~~

~~2533. The board may refuse to issue, or issue subject to terms and conditions, a license on the grounds specified in Section 480; or may suspend, revoke, or impose terms and conditions upon the license of any licensee for any of the following:~~

~~(a) Conviction of a crime substantially related to the qualifications, functions, and duties of a speech-language pathologist or audiologist or hearing aid dispenser, as the case may be. The record of the conviction shall be conclusive evidence thereof.~~

~~(b) Securing a license by fraud or deceit.~~

~~(c) (1) The use or administering to himself or herself, of any controlled substance; (2) the use of any of the dangerous drugs specified in Section 4022, or of alcoholic beverages, to the extent, or in a manner as to be dangerous or injurious to the licensee, to any other person, or to the public, or to the extent that the use impairs the ability of the licensee to practice speech-language pathology or audiology safely; (3) more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of the substances referred to in this section; or (4) any combination of paragraph (1), (2), or (3). The record of the conviction shall be conclusive evidence of unprofessional conduct.~~

~~(d) Advertising in violation of Section 17500. Advertising an academic degree that was not validly awarded or earned under the laws of this state or the applicable jurisdiction in which it was issued is deemed to constitute a violation of Section 17500.~~

~~(e) Committing a dishonest or fraudulent act that is substantially related to the qualifications, functions, or duties of a licensee.~~

~~(f) Incompetence, gross negligence, or repeated negligent acts.~~

~~(g) Other acts that have endangered or are likely to endanger the health, welfare, and safety of the public.~~

~~(h) Use by a hearing aid dispenser of the term “doctor” or “physician” or “clinic” or “audiologist,” or any derivation thereof, except as authorized by law.~~

~~(i) The use, or causing the use, of any advertising or promotional literature in a manner that has the capacity or tendency to mislead or deceive purchasers or prospective purchasers.~~

~~(j) Any cause that would be grounds for denial of an application for a license.~~

1 ~~(k) Violation of Section 1689.6 or 1793.02 of the Civil Code.~~

2 ~~(l) Violation of a term or condition of a probationary order of~~
3 ~~a license issued by the board pursuant to Chapter 5 (commencing~~
4 ~~with Section 11500) of Part 1 of Division 3 of Title 2 of the~~
5 ~~Government Code.~~

6 SEC. 6. ~~Section 2570.19 of the Business and Professions Code~~
7 ~~is amended to read:~~

8 ~~2570.19. (a) There is hereby created a California Board of~~
9 ~~Occupational Therapy, hereafter referred to as the board. The board~~
10 ~~shall enforce and administer this chapter.~~

11 ~~(b) The members of the board shall consist of the following:~~

12 ~~(1) Three occupational therapists who shall have practiced~~
13 ~~occupational therapy for five years.~~

14 ~~(2) One occupational therapy assistant who shall have assisted~~
15 ~~in the practice of occupational therapy for five years.~~

16 ~~(3) Three public members who shall not be licentiates of the~~
17 ~~board, of any other board under this division, or of any board~~
18 ~~referred to in Section 1000 or 3600.~~

19 ~~(c) The Governor shall appoint the three occupational therapists~~
20 ~~and one occupational therapy assistant to be members of the board.~~
21 ~~The Governor, the Senate Committee on Rules, and the Speaker~~
22 ~~of the Assembly shall each appoint a public member. Not more~~
23 ~~than one member of the board shall be appointed from the full-time~~
24 ~~faculty of any university, college, or other educational institution.~~

25 ~~(d) All members shall be residents of California at the time of~~
26 ~~their appointment. The occupational therapist and occupational~~
27 ~~therapy assistant members shall have been engaged in rendering~~
28 ~~occupational therapy services to the public, teaching, or research~~
29 ~~in occupational therapy for at least five years preceding their~~
30 ~~appointments.~~

31 ~~(e) The public members may not be or have ever been~~
32 ~~occupational therapists or occupational therapy assistants or in~~
33 ~~training to become occupational therapists or occupational therapy~~
34 ~~assistants. The public members may not be related to, or have a~~
35 ~~household member who is, an occupational therapist or an~~
36 ~~occupational therapy assistant, and may not have had, within two~~
37 ~~years of the appointment, a substantial financial interest in a person~~
38 ~~regulated by the board.~~

39 ~~(f) The Governor shall appoint two board members for a term~~
40 ~~of one year, two board members for a term of two years, and one~~

1 ~~board member for a term of three years. Appointments made~~
2 ~~thereafter shall be for four-year terms, but no person shall be~~
3 ~~appointed to serve more than two consecutive terms. Terms shall~~
4 ~~begin on the first day of the calendar year and end on the last day~~
5 ~~of the calendar year or until successors are appointed, except for~~
6 ~~the first appointed members who shall serve through the last~~
7 ~~calendar day of the year in which they are appointed, before~~
8 ~~commencing the terms prescribed by this section. Vacancies shall~~
9 ~~be filled by appointment for the unexpired term. The board shall~~
10 ~~annually elect one of its members as president.~~

11 ~~(g) The board shall meet and hold at least one regular meeting~~
12 ~~annually in the Cities of Sacramento, Los Angeles, and San~~
13 ~~Francisco. The board may convene from time to time until its~~
14 ~~business is concluded. Special meetings of the board may be held~~
15 ~~at any time and place designated by the board.~~

16 ~~(h) Notice of each meeting of the board shall be given in~~
17 ~~accordance with the Bagley-Keene Open Meeting Act (Article 9~~
18 ~~(commencing with Section 11120) of Chapter 1 of Part 1 of~~
19 ~~Division 3 of Title 2 of the Government Code).~~

20 ~~(i) Members of the board shall receive no compensation for~~
21 ~~their services, but shall be entitled to reasonable travel and other~~
22 ~~expenses incurred in the execution of their powers and duties in~~
23 ~~accordance with Section 103.~~

24 ~~(j) The appointing power shall have the power to remove any~~
25 ~~member of the board from office for neglect of any duty imposed~~
26 ~~by state law, for incompetency, or for unprofessional or~~
27 ~~dishonorable conduct.~~

28 ~~(k) This section shall remain in effect only until January 1, 2018,~~
29 ~~and as of that date is repealed, unless a later enacted statute, that~~
30 ~~is enacted before January 1, 2018, deletes or extends that date.~~
31 ~~Notwithstanding any other law, the repeal of this section renders~~
32 ~~the board subject to review by the appropriate policy committees~~
33 ~~of the Legislature.~~

34 ~~SEC. 7. Section 2602 of the Business and Professions Code is~~
35 ~~amended to read:~~

36 ~~2602. The Physical Therapy Board of California, hereafter~~
37 ~~referred to as the board, shall enforce and administer this chapter.~~

38 ~~This section shall remain in effect only until January 1, 2018,~~
39 ~~and as of that date is repealed, unless a later enacted statute, that~~
40 ~~is enacted before January 1, 2018, deletes or extends that date.~~

1 ~~Notwithstanding any other provision of law, the repeal of this~~
2 ~~section renders the board subject to review by the appropriate~~
3 ~~policy committees of the Legislature.~~

4 ~~SEC. 8. Section 2607.5 of the Business and Professions Code~~
5 ~~is amended to read:~~

6 ~~2607.5. (a) The board may appoint a person exempt from civil~~
7 ~~service who shall be designated as an executive officer and who~~
8 ~~shall exercise the powers and perform the duties delegated by the~~
9 ~~board and vested in him or her by this chapter.~~

10 ~~(b) This section shall remain in effect only until January 1, 2018,~~
11 ~~and as of that date is repealed, unless a later enacted statute, that~~
12 ~~is enacted before January 1, 2018, deletes or extends that date.~~